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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,967	02/16/2001	Daniel E. Alesi	0100/0118	2936

21395 7590 02/25/2003

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EXAMINER

SERKE, CATHERINE

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/783,967	ALESI, DANIEL E. <i>MP</i>
Examiner	Art Unit	
Catherine Serke	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 December 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 24-52 is/are pending in the application.

4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 39-52 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al (US Pat# 5,746,726) in view of Newby et al (US Pat# 6,436,086).

Sweeney discloses a device that includes a body (52) with a needle (14) extending from one end and another end that is attached to a syringe (fig 3). A housing (36) is hingedly (50) attached to the end of the body having the needle and is pivotable to a position in substantial alignment along the longitudinal axis of the body so as to envelop the needle (fig 2). Locking means (56) are integrated to the housing for fixedly retaining the needle within the housing once the needle is enveloped by the housing (fig 5). The locking means comprises at least one pair of fingers or hooks (56) that prevent the needle from being removed from the housing once the housing is pivoted to envelope the needle (fig 5). Another locking means (58) is on the body that coacts with the locking means on the housing.

Sweeney meets the claim limitations as described above but fails to include the body being connected to tubing instead of a syringe at the other end from the needle. However, Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a) having a needle (206). Additionally, on the opposite side of the body

from the needle is connected flexible tubing (208). The other embodiments show the pivotable housing attached to a syringe and a vacutainer port.

At the time of the invention, it would have been obvious to substitute the syringe of Sweeney for flexible tubing as taught by Newby. The devices are analogous in the art and therefore a combination is proper. Additionally, both devices are functional equivalents and utilize a pivotably hinged housing in order to protect a medical technician from being exposed from a needle stick. The motivation for the incorporation would have been in order to provide the device of Sweeney with an alternate means of blood collection thereby enabling more blood to be collected in a container (i.e. a blood bag) at the end of the flexible tubing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Newby et al.

Newby discloses a safety shield for a medical needle (fig 17) that has a housing (140a) hingedly connected to a body (90a-204) having a needle (206). The proximal portion of the body (204) has wings (see figure 17). Additionally, on the opposite side of the body from the needle is connected flexible tubing (208). A locking mechanism, analogous to applicant's

locking means, is best seen in figure 16. Hooks or fingers (194) hold the housing in the retaining needle position by their connection with element 118.

Response to Arguments

Applicant's arguments filed 12/13/02 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the body as shown in the drawings) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The term body as defined in Merriam Webster's Collegiate Dictionary 10th ed. is the main central or principal part. This term is broad. While one looks to the specification to further elucidate the invention as claimed, the structures from the drawings are not read into the claims. In this case, the prior art does not have to match the "body" structure in the drawings of the instant application. The prior art as applied above has the essential structure and function as the claimed "body". Furthermore, the instant application specification does not devote words to explicitly set forth the unique structure and function of the "body" that would further differentiate the prior art from applicant's "body". The examiner suggests that if the inventive aspect of applicant's invention lies in the "body" then applicant should devote claim language to clearly define the body over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *CS*
February 24, 2003

Brian Casler
BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700